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1.0 Description of the Procedure, Product, or Service

This policy addresses high-dose chemotherapy and allogeneic stem cell support for myelodysplastic diseases and myeloproliferative disorders. Bone marrow transplants typically include high-dose chemotherapy (HDC).

High dose chemotherapy (HDC) involves the administration of cytotoxic agents using doses several times greater than the standard therapeutic dose. Whole body radiotherapy may also be given and included in the term HDC when applicable. The most significant side effect of HDC (also known as myeloablation) is the destruction of the bone marrow and is managed by reinfusion of allogeneic stem cells in order to repopulate the bone marrow.

In some incidences, non-myeloablative treatment protocols are used in conjunction with infusions of allogeneic stem cells. Non-myeloablative regimens do not destroy all of the bone marrow before the transplant is given using the stem cells of a donor. These transplants are also called "mini-transplants" or "transplantlite."

Allogeneic bone marrow transplantation involves harvesting bone marrow or stem cells from a healthy donor (related or unrelated to the recipient) for infusion into a recipient whose bone marrow is compromised. This procedure is an established treatment for certain marrow dysplasias and aplasias and inborn errors of metabolism.

There are three potential sources of allogeneic stem cells.

- a. Bone marrow cells: Bone marrow stem cells can be harvested from a related or unrelated donor.
- b. Peripheral stem cells: Stem cells may be harvested from the peripheral blood circulation. This may involve several pheresis procedures. Pheresis involves withdrawing blood from a donor in which a portion containing stem cells is separated and retained with the remainder retransfused back to the donor.
- c. Umbilical cord blood: Blood harvested from the umbilical cord and placenta shortly after the delivery of neonates contains stem cells. Although cord blood is an allogeneic source, these stem cells are associated with a lower incidence of rejection or graft versus host disease.

Immunologic compatibility between donor and patient is a critical factor for achieving a good outcome of allogeneic bone marrow transplantation. Compatibility is established by serologic tissue typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the HLA, A, B, and DR loci on each leg of chromosome 6. Depending upon the disease being treated, an acceptable donor will match the recipient at all six HLA antigens or most HLA loci.

Myelodysplastic Syndrome (MDS) refers to a group of related bone marrow disorders characterized by impaired maturation of hematopoietic cells and a tendency to transform into acute myelocytic leukemia (AML). The most widely accepted classification system for MDS is the French-American-British (FAB) system that identifies five (5) types of MDS with increasing numbers of circulating blast cells as follows:

- a. Refractory anemia (RA) - fewer than 5% blasts
- b. Refractory anemia with ringed sideroblasts (RARS) - fewer than 5% blasts plus more than 15% ringed sideroblasts
- c. Refractory anemia with excess blasts (RAEB) - 5% to 20% marrow blasts
- d. Refractory anemia with excess blasts in transformation (RAEBT) - 20% - 30% marrow blasts
- e. Chronic myelomonocytic leukemia (CMML) - 1% to 20% blasts and often has characteristics of a myeloproliferative disorder.

Recipients with higher blast counts or complex cytogenetic abnormalities have a greater likelihood of progressing to AML than do other recipients.

Myeloproliferative Disorders are characterized by the slow but relentless expansion of blood producing cells with the potential evolution into a blast crisis similar to AML. Myeloproliferative disorders include the following:

- a. Polycythemia vera (PV)
- b. Essential thrombocythemia (ET)
- c. Primary myelofibrosis also known as agnogenic myeloid metaplasia with myelofibrosis.

Note: Non-myeloablative chemotherapy followed by allogeneic stem cell support may be referred to as a mini transplant.

1.1 Medical Term Definitions

- a. Allogeneic: genetically dissimilar - involves a donor and a recipient; genes are not identical in each organism.
- b. Aplasia: a lack of development of an organ or tissue or of the cellular products from an organ or tissue.
- c. Dysplasia: abnormality of development, in pathology, an alteration in size, shape and organization of adult cells.
- d. Harvesting: to remove tissues or cells from a donor and preserve for transplantation.
- e. Hematopoietic: pertaining to or effecting the formation of blood cells.
- f. Immunologic: pertains to antigens, the immune process and how humans and higher animals fight off disease.
- g. Infuse: the therapeutic introduction of a fluid other than blood into a vein (example: saline solution with a drug added).
- h. Malignant: cancerous, not benign; describes a tumor that invades and destroys the tissues in which it originates and can spread to other sites in the body via the bloodstream and lymphatic system. If untreated, these tumors cause progressive deterioration and death.
- i. Metabolism: sum total of all the chemical reactions occurring in body cells; reaction that transform substances into energy or materials the body can use by means of anabolism or catabolism.

- j. Placenta: Temporary organ formed from both fetal and maternal tissues that provides nutrients and oxygen to the developing fetus, carries away fetal metabolic wastes, and produces the hormones of pregnancy.
- k. Stem cells: immature generic blood cells that will mature into the various types of blood cells in the body.
- l. Umbilical cord: a flexible structure through which the umbilical arteries and vein pass and which connects the fetus to the placenta.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

- a. HDC with HLA matched allogeneic stem cell support may be considered medically necessary as a treatment of myelodysplastic syndromes based on the following:
 1. the recipient has been evaluated and assigned a diagnostic category using the International Prognostic Scoring System (IPSS) for myelodysplastic syndromes; **AND**
 2. the treatment meets the National Comprehensive Cancer Network (NCCN) practice guidelines. Guidelines are available at <http://www.nccn.com/Treatment-Summaries.aspx> (refer to Myelodysplastic Syndromes).
- b. HDC with allogeneic stem cell support may be considered medically necessary as a treatment of myeloproliferative disorders in the following circumstances:
 1. when myeloproliferative disease is associated with progression to myelofibrosis;
 2. when there is an evolution of the disease towards acute leukemia; **OR**
 3. when the disease is complicated by essential thrombocythemia with an associated thrombotic or hemorrhagic disorder.

3.3 Policy Guidelines

- a. HDC and allogeneic stem cell support should be administered through a clinical trial whenever possible.
- b. HDC with stem cell support is typically considered in those recipients with increasing numbers of blasts, signaling a possible transformation to acute myeloid leukemia. Subtypes falling into this category include refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, or chronic myelomonocytic leukemia.
- c. Recipients with refractory anemia with or without ringed sideroblasts may be considered candidates for high dose chemotherapy when chromosomal abnormalities are present or the disorder is associated with the development of significant cytopenias (e.g., neutrophils less $500/\text{mm}^3$, platelets less than $20,000/\text{mm}^3$).
- d. Clinical records should indicate the IPSS Risk category, the biological or chronological age, Performance Status (ECOG 0,1,2), and the recipient has adequate clinical status to undergo AML induction.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Allogeneic bone marrow transplant for myelodysplastic diseases is not covered for myelodysplastic or myeloproliferative disorders other than those listed in **Subsection 3.2**.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior Approval is required for bone marrow transplant allogeneic for myelodysplastic diseases.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**

- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes			
38205	38230	38240	38242

HCPCS Codes
S2150

Note: If prior approval has not been obtained, claims will deny.

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital and Outpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.